AMENDED IN ASSEMBLY AUGUST 13, 2012

AMENDED IN ASSEMBLY JUNE 26, 2012

AMENDED IN SENATE MAY 1, 2012

AMENDED IN SENATE MARCH 26, 2012

SENATE BILL No. 1195

Introduced by Senator Price

February 22, 2012

An act to add Part 6.01 (commencing with Section 12665) to Division 2 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 1195, as amended, Price. Audits of pharmacy benefits.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies by the California State Board of Pharmacy. Existing law provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and for the regulation of health insurers by the Department of Insurance. Existing law requires health care service plan contracts and health insurance policies to provide coverage for specified benefits and requires contracts between plans or insurers and providers to contain provisions requiring a fast, fair, and cost-effective dispute resolution mechanism.

This bill would impose specified requirements on an audit of pharmacy services provided to beneficiaries of a health benefit plan. Among other things, the bill would prohibit the entity conducting the audit from receiving payment on any basis tied to the amount claimed or recovered from the pharmacy.

The bill would require the entity conducting a pharmacy audit to deliver a preliminary audit report to the pharmacy and to give the

pharmacy an opportunity to respond to the report. The bill would require the entity to deliver a final audit report to the pharmacy and to establish, in its contract with the pharmacy, a process for appealing the findings of that report, as specified. The bill would allow either party who, following the appeal, is not satisfied with the appeal, to seek relief under the terms of the contract. The bill would provide that if an identified discrepancy for a single audit exceeds $30,000, future payments to the pharmacy in excess of $30,000 may be withheld pending adjudication of an appeal. The bill would prohibit interest accruing for either party during pendency of the audit, as specified. The bill would require that when the entity is using extrapolation, as defined, in calculating penalties or amounts to be recouped from a pharmacy, that the pharmacy be given an opportunity to provide evidence validating certain orders. The bill also would prohibit a pharmacy from being subject to recoupment of funds for a clerical or recordkeeping error, as defined. The bill would enact other related provisions.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Part 6.01 (commencing with Section 12665) is added to Division 2 of the Insurance Code, to read:

PART 6.01. AUDITS OF PHARMACY BENEFITS

12665. For purposes of this article, the following definitions shall apply:

(a) "Carrier" means a health care service plan, as defined in Section 1345 of the Health and Safety Code, or a health insurer that issues policies of health insurance, as defined in Section 106.

(b) "Clerical or recordkeeping error" includes a typographical error, scrivener's error, or computer error in a required document or record.

(c) "Extrapolation" means the practice of inferring a frequency or dollar amount of overpayments, underpayments, nonvalid claims, or other errors on any portion of claims submitted, based on the frequency or dollar amount of overpayments, underpayments, nonvalid claims, or other errors actually measured in a sample of claims.

(d) "Health benefit plan" means any plan or program that provides, arranges, pays for, or reimburses the cost of health benefits. "Health benefit plan" includes, but is not limited to, a health care service plan contract issued by a health care service plan, as defined in Section 1345 of the Health and Safety Code, and a policy of health insurance, as defined in Section 106, issued by a health insurer.

(e) "Pharmacy" has the same meaning as provided in Section 4037 of the Business and Professions Code.

(f) "Pharmacy audit" means an audit, either onsite or remotely, of any records of a pharmacy conducted by or on behalf of a carrier or a pharmacy benefits manager, or a representative thereof, for prescription drugs that were dispensed by that pharmacy to beneficiaries of a health benefit plan pursuant to a contract with the health benefit plan or the issuer or administrator thereof. "Pharmacy audit" does not include a concurrent review or desk audit that occurs within three business days of transmission of a claim, or a concurrent review or desk audit where no chargeback or recoupment is demanded.

(g) "Pharmacy benefit manager" means a person, business, or other entity that, pursuant to a contract or under an employment relationship with a carrier, health benefit plan sponsor, or other third-party payer, either directly or through an intermediary, manages the prescription drug coverage provided by the carrier, plan sponsor, or other third-party payer, including, but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to prescription drug coverage, contracting with network pharmacies, and controlling the cost of covered prescription drugs.

12665.1. (a) Nothing in this part shall apply to an audit conducted because a pharmacy benefit manager, carrier, health benefit plan sponsor, or other third-party payer has indications that support a reasonable suspicion that criminal wrongdoing, willful misrepresentation, fraud, or abuse has occurred.

(b) Nothing in this part shall apply to an audit conducted by, *or at the direction of,* the California State Board of Pharmacy, the State Department of Health Care Services, the State Department of Public Health, or the Medicare program.

12665.2. Notwithstanding any other provision of law, a contract that is issued, amended, or renewed on or after January 1, 2013, between a pharmacy and a carrier or a pharmacy benefit manager to provide pharmacy services to beneficiaries of a health benefit plan shall comply with the provisions of this part.

12665.3. (a) An entity conducting a pharmacy audit shall not receive payment or any other consideration on any basis that is tied to the amount claimed or actual amount recovered from the pharmacy that is the subject of the audit. Nothing in this subdivision shall be construed to prevent the pharmacy benefit manager or health benefit plan from charging or assessing the plan sponsor, directly or indirectly, based on amounts recouped if both of the following conditions are met:

(1) The plan sponsor and the pharmacy benefit manager or health benefit plan have a contract that explicitly states the percentage charge or assessment to the plan sponsor.

(2) No commission or financial incentive is paid to an agent or employee of the entity conducting the pharmacy audit based, directly or indirectly, on amounts recouped.

(b) A pharmacy shall not be subject to recoupment of funds for a clerical or recordkeeping error, unless the error resulted in actual financial harm to the pharmacy benefit manager, the carrier, or the beneficiary of a health benefit plan.

12665.4. (a) Except as otherwise prohibited by state or federal law, an entity conducting a pharmacy audit shall keep confidential any information collected during the course of the audit and shall not share any information with any person other than the carrier, pharmacy benefit manager, or third-party payer for which the audit is being performed. An entity conducting a pharmacy audit shall have access only to previous audit reports relating to a particular pharmacy conducted by or on behalf of the same entity. Nothing in this subdivision shall be construed to authorize access to information that is otherwise prohibited by law. Nothing in this subdivision shall be construed to prohibit any employer, trust fund, government agency, or any other entity for which the audit is being performed from disclosing its general opinions or conclusions regarding the business practices of the pharmacy based on the audit.

(b) An entity that is not a carrier or pharmacy benefit manager and that is conducting a pharmacy audit on behalf of a carrier or

pharmacy benefit manager shall, prior to conducting the audit, notify the pharmacy in writing that the entity and the carrier or pharmacy benefit manager have executed a business associate agreement or other agreement as required under state and federal privacy laws.

(c) An entity conducting a pharmacy audit shall, prior to leaving a pharmacy at the end of an onsite portion of the audit, provide the pharmacist in charge with a complete list of records reviewed to allow the pharmacy to account for disclosures as required by state and federal privacy laws.

12665.5. (a) An entity conducting an onsite pharmacy audit shall not initiate or schedule a pharmacy audit during the first five business days of any calendar month, unless it is expressly agreed to by the pharmacy being audited.

(b) An entity conducting an onsite pharmacy audit shall provide the pharmacy at least two weeks' prior written notice before conducting an initial audit.

12665.6. (a) A pharmacy audit that involves clinical judgment shall be conducted by, or in consultation with, a licensed pharmacist.

(b) An entity conducting a pharmacy audit shall make all determinations regarding the legal validity of a prescription or other record consistent with determinations made pursuant to Article 4 (commencing with Section 4070) of Chapter 9 of Division 2 of the Business and Professions Code.

(c) Nothing in this section shall be construed to prohibit a pharmacy benefits manager from denying a claim, either in whole or in part, for failure to comply with federal Food *and* Drug Administration or manufacturer requirements, the prescription drug formulary, prior authorization requirements, days' supply requirements, or other coverage or plan design requirement, or for failure to include a National Provider Identification number.

(d) An entity conducting a pharmacy audit shall accept paper or electronic signature logs that document the delivery of pharmacy services to a health plan beneficiary or his or her agent.

12665.7. The time period covered by a pharmacy audit shall not exceed 24 months from the date that the claim was submitted to, or adjudicated by, the pharmacy benefits manager, unless a longer period is required under state or federal law or unless the originating prescription is required.

12665.8. (a) (1) An entity conducting a pharmacy audit shall deliver a preliminary audit report to the pharmacy before issuing a final audit report. This preliminary report shall be issued no later than 60 days after conclusion of the audit.

(2) A pharmacy shall be provided a time period of at least 30 days following receipt of the preliminary audit report under paragraph (1) to respond to the findings in the report, including addressing any alleged mistakes or discrepancies and producing documentation to that effect.

(3) To validate the pharmacy record and delivery, the pharmacy may use authentic and verifiable statements or records, including medication administration records of a nursing home, assisted living facility, hospital, physician and surgeon, or other authorized prescriber, or additional documentation parameters located in the provider manual.

(4) Any legal prescription may be used to validate claims in connection with prescriptions, refills, or changes in prescriptions, including medication administration records, facsimiles, electronic prescriptions, electronically stored images of prescriptions, electronically created annotations, or documented telephone calls from the prescriber or the prescriber's agent. Unless specifically addressed in the audit policies and procedures contained in the contract or provider manual, documentation of an oral prescription order that has been verified by the prescriber shall meet the requirements of this subdivision.

(5) If an entity conducting a pharmacy audit uses extrapolation to calculate penalties or amounts to be recouped, the pharmacy may present evidence to validate orders for dangerous drugs or devices that are subject to invalidation due to extrapolation.

(6) Prior to issuing a final audit report, an entity conducting a pharmacy audit shall take into consideration any response by the pharmacy to the preliminary audit report provided within the timeframes allowed under this section, unless otherwise agreed to by the entity conducting the audit.

(b) (1) An entity conducting a pharmacy audit shall deliver a final audit report to the pharmacy no later than 120 days after receipt of a pharmacy's response to the preliminary audit report.

(2) An entity conducting a pharmacy audit shall establish, in the contract between the pharmacy and the contracting entity, a

process for appealing the findings in a final audit report that complies with the following requirements:

(A) A pharmacy shall be provided a time period of at least 30 days following receipt of the final audit report to file an appeal with the entity identified in the appeal process.

(B) An entity conducting a pharmacy audit shall provide the pharmacy with a written determination of appeal issued by the entity identified in the appeal process, which shall be appended to the final audit report, and a copy of the determination shall be sent to the carrier, health benefit plan sponsor, or other third-party payer.

(C) If, following the appeal, either party is not satisfied with the appeal, the party may seek relief under the terms of the contract.

(c) An entity conducting a pharmacy audit, a carrier, a health benefit plan sponsor, or other third-party payer, or any person acting on behalf of those entities, shall not attempt to make chargebacks or seek recoupment from a pharmacy, or assess or collect penalties from a pharmacy, until the time period for filing an appeal to a final audit report has passed, or until the appeal process has been exhausted, whichever is later. Should the identified discrepancy for a single audit exceed thirty thousand dollars ($30,000), future payments to the pharmacy in excess of thirty thousand dollars ($30,000) may be withheld pending adjudication of an appeal.

(d) Interest shall not accrue during the audit period for either party, beginning with the notice of the audit and ending with the conclusion of the appeal process.

(e) If, following final disposition of a pharmacy audit pursuant to this section, an entity conducting a pharmacy audit, a carrier, a health benefit plan sponsor, or other third-party payer, or any person acting on behalf of those entities, finds that an audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or the unsubstantiated portion thereof without the necessity of any further proceedings.

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